UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALMA CARMICHAEL Plaintiff, v. HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORTION and STRYKER IRELAND LIMITED, Defendants.	COMPLAINT AND JURY DEMAND

COMPLAINT

COMES NOW Plaintiff, Alma Carmichael ("Plaintiff"), by and through the undersigned counsel, and bring this complaint against Defendants, HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORATION and STRYKER IRELAND LIMITED (hereinafter collectively "Defendants" and "Stryker"), and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product(s) sold under the names "The Accolade TMZF® Hip Stem and LFIT Anatomic V40 Femoral Head" (hereinafter, "Defective Devices").

PARTIES, JURISDICTION AND VENUE

2. Plaintiff is a citizen and resident of Salem, Harrison County, West Virginia.

3. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1332.

4. Defendant, Howmedica Osteonics d/b/a Stryker Orthopaedics, is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Mahwah, New Jersey. Defendant does business throughout the United States, including in the State of West Virginia. Defendant Howmedica Osteonics d/b/a Stryker Orthopaedics is a wholly owned subsidiary of parent corporation, Stryker Corporation.

5. Defendant Stryker Corporation is the parent corporation organized and existing under the laws of the State of Michigan, with its principal place of business in Kalamazoo, Michigan. Defendant does business throughout the world and throughout the United States, including the State of West Virginia. Stryker holds itself out as "one of the world's leading medical technologies companies and is dedicated to helping healthcare professionals perform their jobs more efficiently while enhancing patient care. Stryker provides innovative orthopaedic implants as well as state-of-the-art medical and surgical equipment to help people lead more active and more satisfying lives." www.stryker.com.

6. Defendant Stryker Sales Corporation is a corporation organized and existing under the laws of the State of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002 and conducts business throughout the United States, including the State of West Virginia. Stryker Sales Corporation is a wholly owned subsidiary of Stryker Corporation. It employs field representatives throughout the United States. (Source:

http://www.law360.com/articles/408121/stryker-field-service-reps-win-class-cert-in-flsa-suit.)

7. Defendant Stryker Ireland Limited is a foreign corporation that is also a wholly owned subsidiary of Stryker Corporation. Stryker Ireland Limited has three facilities located in Ireland (two in Cork and one in Limerick) and employs approximately 1,200 people in total. These sites are held out at "centers of excellence" in R&D, Manufacturing and Customer Service. Stryker Ireland Limited's product profile includes: Hip Replacement Systems, Knee Replacement Systems, Bone Cement and Precise Cutting Accessories including Micro Rotary instruments and Bone Saw Blades. Stryker develops minimally invasive surgical instruments which are used for cutting, drilling, burring and shaping of bone and soft tissue. Upon information and belief, these products are used during Orthopaedic, Ear Nose and Throat (ENT), Spine, Neuro and Plastic Surgeries. Much of the research and design and manufacturing of the Devices at issue in this litigation occurred at Stryker Ireland Limited before moving the operation to Howmedica Osteonics in Mahwah, New Jersey.

8. The Devices manufactured at Stryker Ireland were sold throughout the United States and in the State of West Virginia. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=110699.

9. Upon information and belief, at all times herein mentioned, the employees of Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of each of the individual Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such designations shall be deemed to mean that the principals, officers, employees, agents and/or representatives of the Defendants committed, knew

of, performed, authorized, ratified and/or directed such transactions on behalf of Defendants while actively engaged in the scope of their duties.

THE PRODUCTS

10. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective products under the name "The Accolade® TMZF Hip Stem and LFIT Anatomic V40 Femoral Head" (hereinafter, "Defective Devices"), either directly or indirectly, to members of the general public within the State of West Virginia, including Plaintiff Alma Carmichael.

11. Defendant's Defective Devices were placed into the stream of interstate commerce and were implanted in Plaintiff Alma Carmichael in October 2011.

12. On March 10, 2015, Plaintiff underwent a revision and explanation of the Defective Devices.

13. As a direct and proximate result of Defendant placing the Defective Products into the stream of commerce, Plaintiff Alma Carmichael has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

14. On March 16, 2000, Defendant received FDA clearance to sell its Accolade prosthetic hip stem in the United States.

15. The Accolade TMZF Stem is a hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to joint disease.

16. The Accolade TMZF Stem is a monoblock, single piece artificial hip

replacement device that is designed to be implanted into the patient's femur. The Accolade TMZF Stem is designed to be used with any number of bearing surface components comprised of the modular ball or artificial femoral head and an acetabular cup or socket.

17. Stryker's L-FIT Anatomic V40 femoral head is one of the modular balls or heads designed to be used with the Accolade TMZF Stem. It is made of chromium/cobalt alloy.

18. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. Howmedica's alloy was designed and patented by Defendant and is different than the titanium alloy employed in the manufacture of prosthetic hip implants. The Defendants claim in their Accolade TMZF Stem promotional materials that TMZF alloy is both stronger and less rigid than other titanium alloys. They also claim that the particular titanium alloy has been tested and proven by Defendants to resist the effects of corrosion and fretting.

19. At all times material hereto, the L-FIT Anatomic V40 femoral head implanted in the Plaintiff was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

20. After the implantation of the Defective Devices, Plaintiff Alma Carmichael began experiencing discomfort in the area of his Defective Devices.

21. Initial diagnostic workup revealed gross failure of the L-FIT Anatomic V40 femoral head and marked elevation of serum cobalt, chromium and titanium.

22. As a result, the Plaintiff was forced to have the device surgically removed. Upon removal, it was apparent the device had failed causing gross deformation of the Accolade TMZF Stem together with severe and permanent tissue and muscle damage.

THE STRYKER ACCOLADE HISTORY

23. In March 2000, Stryker released its Accolade TMZF Hip Stem, the latest evolution in the Company's Meridian Titanium Femoral Stem, the Howmedica Asymmetric Stem Femoral Component, and the Osteonics Omnifit AD-HA Hip Stem Series all cleared for market between the years of 1994 and 1997.

24. According to Stryker's materials, the Accolade TMZF Stem was developed to maximize a patient's hip range of motion, increase stability, and prevent dislocation. These materials also state that the Accolade TMZF Hip Stem is designed to be used with V40 Femoral Heads, which are offered in both forged Vitallium alloy (CoCrMo) and zirconia ceramic. The Accolade TMZF Stem is also designed with two neck angles, the standard 132 degrees and extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The neck lengths are proportional relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

25. The Accolade TMZF Stem combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with plasma sprayed ingrowth/on growth coating of PureFix HA. The LFIT Anatomic V40 Femoral Head was commonly used with the Accolade TMZF Hip Stem. It is made from a chromium/cobalt alloy. Defendants claim that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

26. Despite Defendants' claims, this material combination has been reported to cause corrosion. For decades, scientists have reported the occurrence of accelerated fretting and corrosion issues when dissimilar metals are combined. In their marketing and sale of the device, Defendants represented and warranted that proprietary materials alleviate concerns for this problem.

27. In 2012, Stryker recalled its Rejuvenate and ABG II modular hip systems. These two systems employed the same TMZF titanium metal in the femoral stem. The modular neck of both recalled devices were manufactured from chromium/cobalt. These devices were recalled after reports surfaced indicating excessive device failure due to fretting and corrosion at the taper junction where these dissimilar metals were joined.

28. Patients in whom Stryker Rejuvenate and ABG II hip stems had been implanted were experiencing device failure, symptoms and diagnostic findings identical to Plaintiff, Alma Carmichael. Information disseminated by Stryker at or about the time of the recall cited this failure mechanism as the reason for the recall.

29. Since the recall, revision rates for the Rejuvenate have been reported to exceed 50% in a very short period of time.

30. At or about the same time Stryker recalled the Rejuvenate and ABG II, it redesigned its Accolade TMZF Stem. Stryker abandoned use of TMZF titanium and, instead, its new Accolade II stem is manufactured from a different titanium alloy.

31. Upon information and belief, Stryker has abandoned the use of TMZF titanium through its product line.

32. In addition, Stryker has now recalled a large number of L-FIT Anatomic V40 chromium/cobalt heads. The recall cites gross trunnion failure, metal wear, adverse tissue reaction and the need for revision surgery as causes for recalling the heads. Mrs. Carmichael suffered each of the above and the combination resulted in the need to surgically remove her Accolade TMZF Stem and L-FIT Anatomic V40 head.

CAUSES OF ACTION

COUNT I - NEGLIGENCE

33. Plaintiff realleges and incorporates by reference the allegations set forth above.

34. Defendants designed, manufactured, marketed, detailed, and advertised both the Accolade TMZF Stem and L-FIT Anatomic V40 head to physicians and consumers.

35. As a result, Defendants had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the devices would be implanted.

36. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted and is therefore negligent in the following respects:

a. Defendants failed to adequately design and manufacture the devices to insure that when combined each would not fret, corrode, erode, deteriorate and induce severe metal toxicity in patients. The flaws include but are not limited to:

i. The incompatibility of the TMZF titanium with chromium/cobalt heads;

ii. Use of the TMZF alloy that contains a modulus of elasticity with far inferior stiffness characteristics to other available titanium alloys;

iii. Use of the TMZF alloy with a known corrosion/fretting profile inferior to other titanium alloys;

iv. Poor design of the taper junction between femoral head and neck such that micro motion was predictable;

v. Poor design of the Accolade neck such that the “softer” TMZF alloy would induce suffer from excessive bending and movement;

vi. Poor manufacturing practices such that the taper junction between the femoral head and neck do not “fit” as deigned and intended;

vii. Allowing and promoting the use of large metal heads on Stryker’s small and insufficient V40 trunnion which would predictably lead

to excessive motion, fretting, mechanically assisted crevice corrosion and ultimately device failure; and

viii. A combination of the above factors leads to rapid, severe heavy metal cast off causing soft tissue and bony necrosis, pain and premature failure of the device.

b. Defendants failed to adequately test the "Defective Devices" and their combination to insure they would not fret, corrode, erode, deteriorate and induce severe metal toxicity in the patient;

c. Prior to marketing the "Defective Devices," Defendants failed to conduct anything other than simple, basic bench testing. At the time Defendants designed the "Defective Devices," sufficient scientific art and knowledge existed to conduct testing that would have exposed the defects in the Accolade TMZF Stem when implanted in patients with the chromium/cobalt head;

d. In fact, Stryker has likely conducted testing that reveals the incompatibility of these two materials when used in this design;

e. Defendants made affirmative representations that the "Defective Devices" would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer;

f. Defendants trained its sales force to detail the "Defective Devices" utilizing representations the Defendants knew or should have known to be false, creating in the minds of both surgeons and consumers the belief that the "Defective Devices" were safe for its intended use;

g. Defendants specifically marketed the "Defective Devices" as a safe alternative to metal-on-metal bearing surface "Defective Devices" that had been widely publicized as capable of causing premature failure due to heavy metal toxicity;

h. Defendants failed to manufacture the products to Defendants' own internal specifications such that the taper junction between the neck and stem prematurely failed causing metal debris cast-off and severe metal toxicity in patients;

i. Defendants failed to adequately test the TMZF alloy's compatibility with chromium/cobalt components in an effort to prevent corrosion and fretting at the bearing surface junction of this stem;

j. Defendants failed to promptly act upon reports of failure or warn surgeons such that the device continued to be implanted in combination with chromium/cobalt femoral heads well after it should have been recalled or redesigned; and

k. Defendants chose these materials to be used in combination as a system at a time when safer alternative designs and materials were available.

37. The above conduct exhibits Defendants' failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, debilitating injury that is permanent.

38. As a direct and proximate result of the Defendants' negligence, Plaintiff suffered severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of earning capacity. These damages have occurred in the past and will continue into the future.

COUNT II - BREACH OF EXPRESS WARRANTY

39. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

40. Through its public statements and description of the Accolade Stem and L-FIT Anatomic V40 and its promises relating to the Accolade Stem and L-FIT Anatomic V40, Defendants expressly warranted among other things that the Accolade Stem and L-FIT Anatomic V40 was efficacious and safe for its intended use and was designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity to or over competing products.

41. Through its public statements and descriptions of the L-FIT Anatomic V40 heads and its promises relating to the these heads, Defendants expressly warranted among other things

that the L-FIT Anatomic V40 heads were efficacious and safe for their intended use and were designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity to or over competing products.

42. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Accolade TMZF Stem and L-FIT Anatomic V40 heads, but which contained material misrepresentations and failed to warn of the risks of the Accolade TMZF Stem and L-FIT Anatomic V40 heads; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the Accolade TMZF Stem and L-FIT Anatomic V40 heads and the downplaying of the risks associated with the Accolade TMZF Stem and L-FIT Anatomic V40 heads; and (iv) false and misleading written information supplied by Defendants.

43. Plaintiff further alleges that all of the aforementioned written materials are known to Defendants and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendants and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

44. When Defendants made these express warranties, Defendants knew the purpose for which Accolade TMZF Stem and L-FIT Anatomic V40 heads were to be used and warranted them to be in all respects safe and proper for such purpose including their use in combination.

45. Defendants drafted the documents and/or made the statements upon which these warranty claims are based, and in so doing, defined the terms of those warranties.

46. The Accolade TMZF Stem and L-FIT Anatomic V40 heads do not conform to Defendants' representations in that their use in combination is not safe and produces serious side

effects.

47. As such, the Accolade TMZF Stem and L-FIT Anatomic V40 heads did not conform to Defendants' promises, descriptions or affirmations of fact and were not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such "Defective Devices" are used.

48. Defendants, therefore, breached their express warranties to Plaintiff in violation of both West Viriginia statutory and common law by manufacturing, marketing and selling the Accolade TMZF Stem and L-FIT Anatomic V40 heads to Plaintiff causing damages as will be established at trial.

COUNT III - STRICT LIABILITY - FAILURE TO WARN

49. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

50. The Accolade TMZF Stem implanted into Plaintiff contained no warnings or, in the alternative, inadequate warnings as to the risk that the product could cause significant heavy metal toxicity.

51. The Accolade TMZF Stem implanted into Plaintiff contained no warnings that it should not be implanted with chromium/cobalt femoral heads which posed significant increased risk of fretting, corrosion and heavy metal toxicity in patients.

52. The warnings that accompanied the Accolade TMZF Stem failed to provide that level of information that an ordinary consumer would expect when using the Accolade implant in a manner reasonably foreseeable to the Defendants.

53. The corollary is also true. The L-FIT Anatomic V40 head implanted into Plaintiff

contained no warnings as described in paragraphs 44 – 46.

54. Had Plaintiff or his surgeon received a proper or adequate warning as to the risks associated with using the Accolade and L-FIT Anatomic V40 heads, the product would not have been used.

55. Reasonable and adequate alternatives to chromium/cobalt femoral heads existed at the time Plaintiff was implanted with his Accolade TMZF Stem and L-FIT Anatomic V40 heads.

56. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Accolade TMZF Stem and its combination with chromium/cobalt femoral heads, he would not have recommended the device; would have used an alternate device or at a minimum, provided Plaintiff with adequate warning and obtained his informed consent. As stated above, had Plaintiff received an adequate warning, Plaintiff would not have agreed to have the Accolade implanted or would have demanded that the Accolade be combined with a ceramic femoral head.

57. The failure to warn of the Accolade and L-FIT Anatomic V40 head's risks caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damages and losses will continue in the future.

COUNT IV - STRICT LIABILITY - DESIGN DEFECT

58. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

59. This is an action based upon design defect against Defendants.

60. Integral to the design of the Accolade TMZF Stem was its compatibility with Stryker's chromium/cobalt L-FIT Anatomic V40 femoral heads.

61. Defendants' Accolade TMZF Stem is designed in such a way that, when used as intended in combination with L-FIT Anatomic V40 chromium/cobalt femoral heads, it causes serious, permanent and devastating damage to patients in which it is implanted. The damage and mechanism of injury have been previously described.

62. When combined with L-FIT Anatomic V40 chromium/cobalt femoral heads, Defendants' Accolade TMZF Stems do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

63. The risks of using Defendants' Accolade TMZF Stems in combination with L-FIT Anatomic V40 heads chromium/cobalt femoral heads outweigh the benefits of using them.

64. The Accolade TMZF Stem and L-FIT Anatomic V40 head installed in Plaintiff's hip was defectively designed.

65. The design defect in Defendants' Accolade TMZF Stem and L-FIT Anatomic V40 head caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

COUNT V - STRICT LIABILITY - MANUFACTURING DEFECT

66. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

67. This is an action based on a manufacturing defect against the Defendants.

68. The Accolade TMZF Stem and L-FIT Anatomic V40 heads are designed for implantation into the human body and to last fifteen or more years. They are also designed to be compatible with human tissue and bone.

69. The Accolade TMZF Stem and L-FIT Anatomic V40 head implanted in the Plaintiff prematurely failed as previously described.

70. The Accolade TMZF titanium stem was manufactured in a substandard manner such that either:

a. The tapers were poorly manufactured so that they did not "fit;"

b. The TMZF titanium material was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment;

c. The TMZF titanium material was fashioned in such a manner that it did not maintain structural integrity when mated with a chromium/cobalt femoral head;

d. The chromium/cobalt femoral head was manufactured such that it did not "fit;"

e. The chromium/cobalt femoral head was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment; and

f. The chromium/cobalt femoral head was fashioned in such a manner that it did not maintain structural integrity when mated with a chromium/cobalt femoral head.

71. This combination was not compatible with human tissue and bone. Through a

process of fretting and corrosion, it released heavy metals into the Plaintiff's body causing severe and permanent destruction of bone and tissue. Defendants failed to manufacture the product in a manner that prevented fretting and corrosion and, in fact, manufactured the product such that it caused fretting and corrosion.

72. The Accolade TMZF Stem and L-FIT Anatomic V40 head installed in Plaintiff's hip contained a manufacturing defect.

73. The manufacturing defect in the Accolade TMZF Stem and L-FIT Anatomic V40 head caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against the Defendants as follows:

a. Awarding compensatory damages resulting from Defendants' breach of warranty, negligence and for strict liability.

b. Awarding loss of consortium damages.

c. Awarding actual damages to the Plaintiff Alma Carmichael incidental to Alma Carmichael's purchase and use of the Accolade TMZF Stem in an amount to be determined at trial;

d. Awarding punitive damages to the Plaintiff;

e. Awarding pre-judgment and post-judgment interest to the Plaintiff;

f. Awarding the costs and the expenses of their litigation to the Plaintiff;

g. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

h. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

Respectfully submitted,

NAPOLI SHKOLNIK ,PLLC

Dated: March 10, 2017

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